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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/545,283	04/07/2000	Bryan J. Boyle	HYS-5	1585

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EXAMINER
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ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/22/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/545,283	Boyle et al
Examiner	**Art Unit**
Jehanne Souaya	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 29, 2002*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *10, 11, 20, and 30-32* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *10, 11, and 20* is/are allowed.

6) ☒ Claim(s) *30-32* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 17
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Currently, claims 10, 11, 20, 30, 31, and newly added claim 32 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejections of claims 10-11, 20, and 30-31 made under 35 USC 101 and 35 USC 112/first paragraph regarding enablement are withdrawn in view of applicant's response and declaration filed 7/25/2002. Specifically, the response shows that SEQ ID NO 4 exhibits 99% sequence identity with BDCA-2, blood dendritic cell antigen 2. Although the specification does not teach such identity to BDCA-2, the art teaches that BDCA-2 serves as a marker for dendritic cells. Such specific and substantial utility as a marker for dendritic cell populations is supported by the specification's disclosure that SEQ ID NO 4 is also homologous to another C-type lectin receptor, DCIR which the specification teaches is a dendritic cell immunoreceptor.

Drawings

4. It is noted that the response to the previous office action does not indicate whether the corrected Fig 4, found in exhibit 1 of the declaration was a proposed drawing correction or an actual new drawing, therefore, it has been evaluated as a "proposed drawing correction". The proposed drawing correction filed on July 25, 2002 has been reviewed and would be sufficient to overcome the objection to the drawings made in the previous office action. Corrected drawings for each figure (as corrected for proposed "Fig 4" in exhibit 1) are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Maintained Rejections

Claim Rejections - 35 USC § 112

5. The rejection of claim 31 made under 35 USC 112/2nd paragraph, is maintained because the response did not contain a clean version of the claims as well as a marked up copy of the claims (the response only included 2 marked up copies of the claims). The non-entered amendment to claim 31 would be sufficient to overcome the rejection if a clean version of said claim is included.

New Grounds of Rejection

Written Description

6. Claim 30 and newly added claim 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following rejection contains grounds maintained from the previous office action with regard to claim 30 and newly applied with regard to newly added claim 32.

With regard to claim 30 and newly added claim 32, the claims are drawn to a polypeptide sequence which is 99% identical or 90% identical, respectively, to the amino acid of SEQ ID NO 4 or SEQ ID NO 6. Such a recitation encompasses mutants of SEQ ID NO 4 or 6 as well as variants of SEQ ID NOS 4 or 6 without altered function. The specification, however, does not teach what the function or activity of SEQ ID NO 4 or 6, nor does the specification teach which amino acids can be altered such that the function of SEQ ID NO 4 or 6 are altered, or remain intact. The specification only teaches that SEQ ID NO 4 possesses sequence identity to a few C-type lectin like receptors and asserts the C-type lectin receptor-like proteins of the invention belong to the same family as C-type lectin receptor, mannose-binding lectins, mammon-binding lectins, and dendritic cell immunoreceptors and therefore have similar activity to these C-type lectin receptor proteins. C-type lectin receptors, however, belong to a large family of proteins exhibiting different structures and functions, such that an analysis based solely on homology or membership in a broad family does not identify the ligand or biological activity or function of SEQ ID NO 4. Balch et al (JBC, 1998, vol. 273, pp 18656-18664) teaches that comparative sequence analysis suggests that "mouse macrophage C-type lectin" (referenced as mMCL by Balch, and which possesses 39% amino acid identity to SEQ ID NO 4) has carbohydrate binding

capabilities, but that little can be postulated about the ability or specificity of mMCL from its protein sequence alone because even within a relatively small, conserved domain, binding specificity can be altered with the mutation of only one or two amino acids (see Iobst and Drickamer, JBC, 1994, vol. 269, pp 15512-15519). Balch further teaches that some molecules containing C-type lectin domains have been shown to bind peptide sequences such that this versatility makes predicting putative ligands for this type of lectin domain difficult. Therefore, since the specificity, biological activity or function of SEQ ID NOS 4 or 6 have not been taught, and the art clearly teaches that homology analysis alone does not make clear the function of a C-type lectin receptor, the recitation of 99% identity encompasses mutants and variants that have not been described by the specification. Further, the recitation of 90% identity further encompasses homologs and allelic variants from any source, that have not been described by the specification. The recitation of the amino acid sequences of SEQ ID NOS 4 and 6 is not representative of the functionally different proteins from this broad class, nor do the teachings in the specification make clear to the skilled artisan which amino acids can be changed to result in either a protein with similar or altered activity to the polypeptides of SEQ ID NOS 4 or 6.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of polypeptides comprising the sequence of SEQ ID NOS: 4 or 6 or a polypeptide encoded by a polynucleotide comprising the sequence of SEQ ID NO 3, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or isolating it. The polypeptide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Accordingly, the specification does not provide a written description of the invention of claim 30 and newly added claim 32.

Response to Arguments

The response traverses the rejection. The response traverses that the production of a number of species that are encompassed within the claimed genus is described throughout the specification, for example, at page 34, line 25, to page 36, line 29. This argument has been thoroughly reviewed but was not found persuasive because the specification does not teach the sequences of such species nor does the specification teach which amino acids can be altered with or without altering the activity or function of the protein of SEQ ID NO 4. As stated above, with the exception of polypeptides comprising the sequence of SEQ ID NOS: 4 or 6 or a polypeptide encoded by a polynucleotide comprising the sequence of SEQ ID NO 3, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or isolating it. The polypeptide itself is required.

The response further traverses that applicants have not relied solely on analysis based solely on homology or membership in a broad family, but provide herewith data from PCR studies of mRNA expression and Western Blot analysis to confirm the function or activity shared in common with other members of the C-type lectin receptor family, and more specifically the type II member, BDCA-2. This argument has been thoroughly, but was found persuasive only in part. The written description rejection has been withdrawn with respect to the points raised in the previous office action with regard to whether SEQ ID NO 4 is a full length protein because

exhibit 4 asserts that SEQ ID NO 4 is a full length ORF. However, the response was not found persuasive as to a sufficient number of species of the claimed genus being taught by the specification. Furthermore, the references cited above exemplify the difficulty of altering a single amino acid in a C-lectin receptor protein. Balch et al (JBC, 1998, vol. 273, pp 18656-18664) teaches that comparative sequence analysis suggests that "mouse macrophage C-type lectin" (referenced as mMCL by Balch, and which possesses 39% amino acid identity to SEQ ID NO 4) has carbohydrate binding capabilities, but that little can be postulated about the ability or specificity of mMCL from its protein sequence alone because even within a relatively small, conserved domain, binding specificity can be altered with the mutation of only one or two amino acids (see Iobst and Drickamer, JBC, 1994, vol. 269, pp 15512-15519). Although SEQ ID NO 4 exhibits 99% identity to BDCA-2, neither the specification nor the art teach which amino acids in either SEQ ID NO 4 or BDCA-2 can be altered or deleted such that the skilled artisan could envision what the detailed chemical structure of a variant or homolog of SEQ ID NO 4 with altered or maintained function or activity would look like. For these reasons and the reasons made of record above and in previous office action, the rejection is maintained.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Claims 10, 11, 20, and 31 are free of the prior art.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634
October 15, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600